Amendment to the Claims:

Please amend the claims as follows.

This listing of claims will replace all prior versions, and listing, of claims in the application: Listing of Claims:

Claim 1 (currently amended): A method for treating myeloma, comprising:

(A) (a) providing an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor;

- (b) providing a nitrogen mustard anticancer agent; and
- (c) administering the [[a]] nitrogen mustard anticancer agent in combination with the [[an]] anti-IL-6 receptor antibody as part of a treatment regimen,

wherein the <u>co-administration of</u> nitrogen mustard anticancer agent <u>and the anti-IL-6</u>

<u>receptor antibody has a higher (synergistic) is administered in an amount to enhance the</u> therapeutic

effect <u>for myeloma than when</u> [[of]] the anti-IL-6 receptor antibody <u>alone is administered or when</u>

the nitrogen mustard anticancer agent alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the nitrogen mustard anticancer agent are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the nitrogen mustard anticancer agent are formulated in one pharmaceutical composition.

Claim 2 (currently amended): The method according to claim 1, wherein the anti-IL-6 receptor antibody <u>comprises</u> [[is]] a monoclonal antibody.

Claim 3 (currently amended): The method according to claim 2, wherein the monoclonal antibody comprises [[is]] a PM-1 antibody deposited as FERM BP-2998.

Claim 4 (currently amended): The method according to claim 3, wherein the PM-1 antibody comprises [[is]] a reshaped human PM-1 antibody.

sd-363366 2

Claim 5 (currently amended): The method according to claim 1, wherein the nitrogen mustard anticancer agent <u>comprises</u> [[is]] mechlorethamine, nitrogen mustard N-oxide, melphalan, uramustin, ifosfamide, chlorambucil, or cyclophosphamide, or a combination thereof.

Claim 6 (currently amended): The method according to claim 1, wherein (a) the nitrogen mustard anticancer agent is melphalan and the anti-IL-6 receptor antibody and nitrogen mustard anticancer agent provide a synergistic effect; or, (b) the method of (a), wherein the melphalan is administered as an oral administration of 1 to 20 mg per day, every day or 1 to 6 times per week, or as high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 7 (currently amended): A method for treating myeloma, comprising

(A) administering an anti-IL-6 receptor antibody in combination with a nitrogen mustard anticancer agent as part of a treatment regimen,

wherein the anti-IL-6 receptor antibody or the nitrogen mustard anticancer agent is administered in an amount to <u>have a higher (synergistic)</u> enhance the therapeutic effect for myeloma than when [[of]] the nitrogen mustard anticancer agent is administered alone, or when the anti-IL-6 receptor antibody is administered alone; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the nitrogen mustard anticancer agent are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the nitrogen mustard anticancer agent are formulated in one pharmaceutical composition.

Claim 8 (currently amended): The method according to claim 7, wherein the anti-IL-6 receptor antibody comprises [[is]] a monoclonal antibody.

Claim 9 (currently amended): The method according to claim 8, wherein the monoclonal antibody comprises [[is]] a PM-1 antibody deposited as FERM BP-2998.

sd-363366 3

Claim 10 (currently amended): The method according to claim 9, wherein the PM-1 antibody comprises [[is]] a reshaped human PM-1 antibody.

Claim 11 (currently amended): The method according to claim 7, wherein the nitrogen mustard anticancer agent <u>comprises</u> [[is]] mechlorethamine, nitrogen mustard N-oxide, melphalan, uramustin, ifosfamide, chlorambucil, or cyclophosphamide, <u>or a combination thereof.</u>

Claim 12 (currently amended): The method according to claim 7, wherein the nitrogen mustard anticancer agent <u>comprises</u> [[is]] melphalan and the anti-IL-6 receptor antibody and nitrogen mustard anticancer agent provide a synergistic effect.

Claim 13 (new): The method of claim 12, wherein the melphalan is administered as an oral administration of 1 to 20 mg per day, every day or 1 to 6 times per week, or as high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 14 (new): The method of claim 12, wherein a pharmaceutical composition comprising a nitrogen mustard anticancer agent is administered simultaneously with the anti-IL-6 receptor antibody, and the ratio, is, when combined with daily oral administration of melphalan, 0.01 to 1000 fold (weight ratio) relative to the dose of melphalan.

Claim 15 (new): The method of claim 1, wherein a pharmaceutical composition comprising a nitrogen mustard anticancer agent is administered orally, by intravenous injection, drip infusion, intraarterial injection, intramuscular injection, intratumor injection, intrathoracic injection, or intraperitoneal injection, either systemically or locally.

Claim 16 (new): The method of claim 1, wherein a pharmaceutical composition comprising anti-IL-6 receptor antibody is administered parenterally, by intravenous injection, drip infusion, intramuscular injection, intraperitoneal injection, subcutaneous injection, either systemically or locally; or, is administered as local dosage-forms, external preparations, local injections; or, as

sd-363366

external preparations, liniments, ointments, gel, cream, emulsions, and liquids, tapes, plaster tapes, patches, nebulas, sprays or powders.

Claim 17 (new): A method for treating a myeloma comprising:

- (A) (a) providing at least one pharmaceutical composition comprising separately or in combination:
- (i) an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor, and
 - (ii) a nitrogen mustard anticancer agent comprising melphalan; and
- (b) administering to an individual in need thereof the pharmaceutical composition as part of a treatment regimen,

wherein the co-administration of nitrogen mustard anticancer agent and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the nitrogen mustard anticancer agent alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the nitrogen mustard anticancer agent are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the nitrogen mustard anticancer agent are formulated in one pharmaceutical composition.

Claim 18 (new): The method of claim 1, wherein treating myeloma comprises a life elongation effect.

Claim 19 (new): The method of claim 7, wherein treating myeloma comprises a life elongation effect.

Claim 20 (new): The method of claim 17, wherein treating myeloma comprises a life elongation effect.

5

sd-363366